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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/628,296	07/28/2003	Lian-Chao Li	P06331US01	4176
27407 7590 06/12/2007 MCKEE, VOORHEES & SEASE, P.L.C. ATTN: PENNSYLVANIA STATE UNIVERSITY 801 GRAND AVENUE, SUITE 3200 DES MOINES, IA 50309-2721			EXAMINER KUMAR, VINOD	
			ART UNIT 1638	PAPER NUMBER
			MAIL DATE 06/12/2007	DELIVERY MODE PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

## Office Action Summary

Application No.

10/628,296

Applicant(s)

LI ET AL.

Examiner

Vinod Kumar

Art Unit

1638

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 04 May 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 30 and 35 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 30 and 35 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 28 July 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: \_\_\_\_\_

## **DETAILED ACTION**

### ***Status of objections and rejections***

1. Office acknowledges the receipt of Applicant's request for continued examination (RCE) filed on May 4, 2007. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action. All previous claim rejections not set forth below have been withdrawn in view of claim amendments. Claims 30 and 35 are pending. Claims 30 and 35 are examined on merits in this Office action.

### ***Election/Restriction***

2. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

### ***Claim Rejections - 35 USC § 112***

3. Claims 30, and 35 remain rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a solution comprising an isolated group 2/3 pollen allergen of SEQ ID NO: 2 (Lol p 3) having  $\beta$ -expansin activity, and  $\beta$ -expansin Lol p1, wherein group 2/3 pollen allergen of SEQ ID NO: 2 and  $\beta$ -expansin Lol p1 synergistically expand monocot cell walls, does not reasonably provide enablement for a solution comprising SEQ ID NO: 2 with any  $\beta$ -expansin other than Lol p1. The specification does not enable any person skilled in the art to which it pertains, or with

which it is most nearly connected, to use the invention commensurate in scope with these claims for the reasons of record stated in Office action mailed on November 14, 2006. Applicants traverse the rejection as applied to claims 30-37 (31-34, and 36-37, now cancelled) in the paper filed on February 12, 2007.

Applicants argue that those of ordinary skill in the art would be familiar with routine techniques and standards of determining beta expansin activity. Applicants further argue that there is no requirement that every possible combination of group 2/3 allergen and  $\beta$ -expansin act synergistically on expanding monocot cell walls. Applicants further argue that the testing of the group 2/3 allergen or other  $\beta$ -expansin polypeptide or protein sequences for beta expansin activity is straightforward and known to one skilled in the art (response, last paragraph bridging the pages 5 and 6 through the end of page 6).

Applicant's arguments were fully considered as they apply to amended claims 30 and 35 but were not found persuasive. Claim 30 is directed to any  $\beta$ -expansin which is not a group 2/3 pollen allergen but having  $\beta$ -expansin activity. While the specification provides guidance on using SEQ ID NO: 2 with Lol p1 expansin, it does not enable all other  $\beta$ -expansins which are not group 2/3 pollen allergens. Cosgrove (Current Opinion in Plant Biology, 3:73-78, 2000) teach existence of  $\beta$ -expansins in plants with unknown function. The reference further teaches that some plant derived  $\beta$ -expansins may be involved in cytokinin-mediated cell proliferation, and their role in cell wall elongation remain elusive. In the absence of guidance, undue experimentation by one skilled in art would have been required at the time the claimed invention was made to isolate other  $\beta$ -expansins which are not group 2/3 allergen and which would expand monocot cell

walls synergistically when used with instant SEQ ID NO: 2. See In re Bell, 26 USPQ2d 1529, 1532 (Fed. Cir. 1993) and In re Deuel, 34 USPQ2d, 1210 (Fed. Cir. 1995), which teach that the mere existence of a protein does not enable claims drawn to a nucleic acid encoding that protein. See also Amgen Inc. v. Chugai Pharmaceutical Co. Ltd., 18 USPQ2d 1016 at page 1027, where it is taught that the disclosure of a few gene sequences did not enable claims broadly drawn to any analog thereof.

4. Claims 30 and 35 remain rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention for the reasons of record stated in Office action mailed on November 14, 2006. Applicants traverse the rejection as applied to claims 30-37 (31-34, and 36-37, now cancelled) in the paper filed on February 12, 2007.

Applicants argue that the specification provides detailed guidance to one skilled in the ordinary art to make, isolate, and identify  $\beta$ -expansins and test these proteins for beta expansin activity. Applicants further argue that the specification provides guidance on relevant identifying characteristics, and thus one skilled in the art would be able to test said expansins for expansin activity (response, page 8, lines 5-15).

Applicant's arguments were fully considered but were not found to be persuasive. Claim 30 is directed to any  $\beta$ -expansin which is not a group 2/3 pollen allergen but having  $\beta$ -expansin activity.

The Federal Circuit has recently clarified the application of the written description

requirement. The court stated that a written description of an invention "requires a precise definition, such as by structure, formula, [or] chemical name, of the claimed subject matter sufficient to distinguish it from other materials." *University of California v. Eli Lilly and Co.*, 119 F.3d 1559, 1568; 43 USPQ2d 1398, 1406 (Fed. Cir. 1997). The court also concluded that "naming a type of material generally known to exist, in the absence of knowledge as to what that material consists of, is not a description of that material." *Id.* Further, the court held that to adequately describe a claimed genus, Patent Owner must describe a representative number of the species of the claimed genus, and that one of skill in the art should be able to "visualize or recognize the identity of the members of the genus." *Id.*

Finally, the court held:

A description of a genus of cDNAs may be achieved by means of a recitation of a representative number of cDNAs, defined by nucleotide sequence, falling within the scope of the genus or a recitation of structural features common to members of the genus, which features constitute a substantial portion of the genus. *Id.*

See also MPEP Section 2163, page 174 of Chapter 2100 of the August 2005 version, column 1, bottom paragraph, where it is taught that

[T]he claimed invention as a whole may not be adequately described where an invention is described solely in terms of a method of its making coupled with its function and there is no described or art-recognized correlation or relationship between the structure of the invention and its function. A biomolecule sequence described only by a functional characteristic, without any known or disclosed correlation between that function and the structure of the sequence, normally is not a sufficient identifying characteristic for written description purposes, even when accompanied by a method of obtaining the claimed sequence.

See also *Amgen Inc. v. Chugai Pharmaceutical Co. Ltd.*, 18 USPQ 2d 1016 at 1021, (Fed. Cir. 1991) where it is taught that a gene is not reduced to practice until the inventor can define it by "its physical or chemical properties" (e.g. a DNA sequence).

The specification does not have adequate written description for a genus of  $\beta$ -expansins which are not a group 2/3 pollen allergens but are having  $\beta$ -expansin activity under current written description guidelines. Specification does not describe these undisclosed structures of Applicant's broadly claimed genus and one skilled in the art cannot reliably predict the structure of these sequences based upon the disclosure. Lol p

1. Furthermore, said structures of Applicant's broadly claimed genus are not correlated to the function expanding monocot cell walls when used synergistically with SEQ ID NO:
2. Furthermore, Applicants have failed to describe conserved functional domains that are shared by these undisclosed structures of their broadly claimed genus. Applicants have failed to reduce their broadly claimed genus to practice.

Accordingly, there is lack of adequate description to inform a skilled artisan that applicant was in possession of the claimed invention at the time of filing. See Written Description guidelines published in Federal Register/Vol.66, No. 4/Friday, January 5, 2001/Notices; p. 1099-1111.

Given the claim breadth and lack of guidance as discussed above, the specification does not provide written description of the genus broadly claimed. Accordingly, one skilled in the art would not have recognized Applicants to have been in possession of the claimed invention at the time of filing.

5. Claims 30 and 35 remain rejected under 35 U.S.C. 102(b) as being anticipated by Ansari et al. (Biochemistry, 28:8665-8670, 1989) taken with the evidence of Li et al. (US Patent Publication No. US204/0110190) for the reasons of record stated in the Office action mailed on November 14, 2006. Applicants traverse the rejection as applied to claims 30-37 (31-34, and 36-37, now cancelled) in the paper filed on February 12, 2007.

Applicants argue that claim 30 has been amended so that it now recites "an isolated group 2/3 pollen allergen of SEQ ID NO: 2 having  $\beta$ -expansin activity, wherein said  $\beta$ -expansin is not a group 2/3 allergen, and wherein the group 2/3 pollen allergen and the  $\beta$ -expansin in combination synergistically expand monocot cell walls". Applicants further argue that Ansari et al. fail to anticipate the amended claim (response, page 10, lines 1-10).

Applicant's arguments were fully considered as they apply to the amended claims but were not found persuasive. It is maintained that Ansari et al. disclose a protein preparation from rye grass pollen comprising a pollen extract which comprises a group 2/3 pollen allergen (100% sequence identity to instant SEQ ID NO: 2) and Lol p1 ( $\beta$ -expansin, which is not group 2/3 pollen allergen). The property of synergistically expanding monocot cell walls is inherent to the protein preparation (pollen extract) comprising a group 2/3 pollen allergen of SEQ ID NO: 2 and said Lol p1 proteins. This is further evidenced by Li et al. who disclose inherent properties of synergistically expanding monocot cell by a protein preparation comprising SEQ ID NO: 2 and said Lol p1. Furthermore, the property of  $\beta$ -expansin activity is inherent to Lol p III (100% identity with instant SEQ ID NO: 2) and Lol p1 proteins disclosed in the reference.



Furthermore, the property of expansin activity which is not affected by DTT is also inherent to the polypeptide Lol p III disclosed in the reference as evidenced by the absence of cysteine residues in the amino acid sequence for Lol p III disclosed in the reference.

Accordingly, Ansari et al. anticipated the claimed invention.

### ***Summary***

6. Claims 30, and 35 are rejected.

### ***Contact Information***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Vinod Kumar whose telephone number is (571) 272-4445.

The examiner can normally be reached on 8.30 a.m. to 5.00 pm.  
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anne Marie Grunberg can be reached on (571) 272-0975. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



PHUONG T. BUI  
PRIMARY EXAMINER